

North Carolina Herald Study

A population-based pilot in support of the NCS

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**US Department of Health
and Human Services**
NIH, CDC, NCHS, OS



**US Environmental
Protection Agency**
ORD, OCHP



Background and History

- Federal plans for the NCS gained momentum in 2000
 - Recognized need for pilot test capacity
- EPA worked with NIH, CDC and the Office of the Secretary DHHS to develop a comprehensive scope of work in 2001
 - Ability to execute longitudinal study
- Competitive EPA contract awarded to RTI, International in 2002
- Expert Panel Sampling Workshop in 2004 recommended pilot test of recruitment

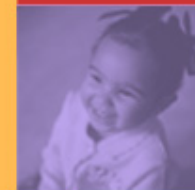


Pilot Study Concepts

- Longitudinal Cohort design
- Testing protocols and procedures for use in the National Children's Study
 - Sample selection, and community engagement
 - Census tracts vs. school catchment areas
 - Household enumeration
 - Commercially available mailing lists vs. counting and listing
 - Differing strategies needed for rural areas and urban areas
 - Achieving the cooperation of local medical facilities
 - What are reasons for participating/withdrawing from study?

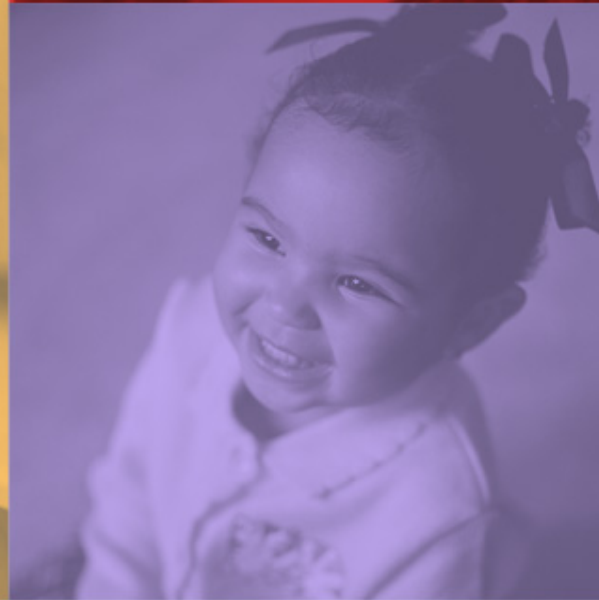


Priority Outcomes



- Response rates
 - Urban vs. Rural
 - Census vs School Catchment
 - Preconception, Pregnancy, and Birth
- What parts of the study have the highest acceptance and disapproval
- Health
 - Birth Outcomes
 - Variations in Normal Developmental





Sample Design and Implementation



Study Locations

- Counties
 - Not already selected for the NCS
 - Close to study investigators
 - 1 rural
 - 1 urban
- Study segments (2 per county)
 - 1 census tract
 - 1 school catchment area



How were counties selected?

- Evaluated all NC counties with a focus on 150 mile radius from RTP
- Examined census data with a focus on variation in income, race/ethnicity
- Evaluated births to hospitals in and out of each county
- Ease of access to school data
- Purposive sample to best generalize to full NCS
- Local community connections



National Children's Study Locations

Vanguard locations: Study Centers awarded (bold)

Vanguard locations: Study Centers pending award (*italic*)

Lincoln, Pipestone, and Yellow Medicine Counties, Minnesota
and Brookings County, South Dakota

Salt Lake County
Utah

Waukesha County
Wisconsin

New York City (Queens)
New York

Montgomery County
Pennsylvania

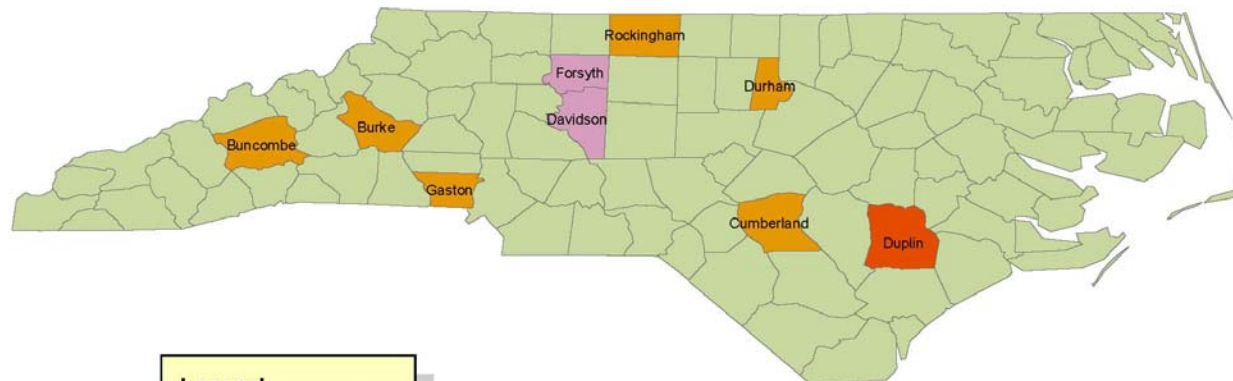
Orange County
California

Duplin County
North Carolina

Orange County
Florida

North Carolina NCS locations

National Children's Study (NCS)



Legend

- Pilot Study Counties
- NCS Counties
- Vanguard County

0 25 50 100
Miles

Projection Information:
Geographic Coordinate System
North American Datum 1983



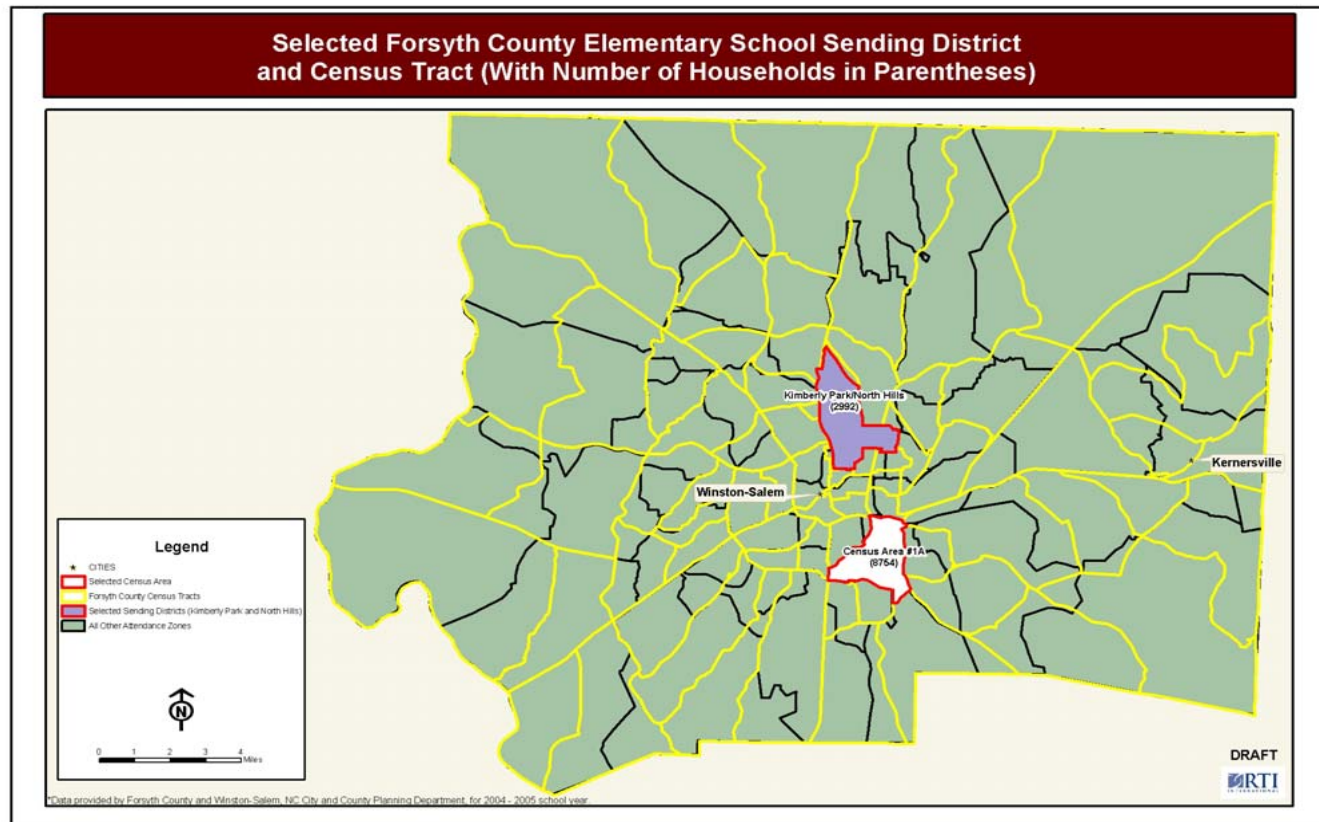
Process for selection - segments

- Base maps of census boundaries and school catchment areas
- School maps had to be created and segments drawn
 - Split school areas too large
 - Combine contiguous schools too small
- Descriptive tables of census data and estimated demographics based on weighted census data (centroid)
- Assembled sets of contiguous units of ~2500 households



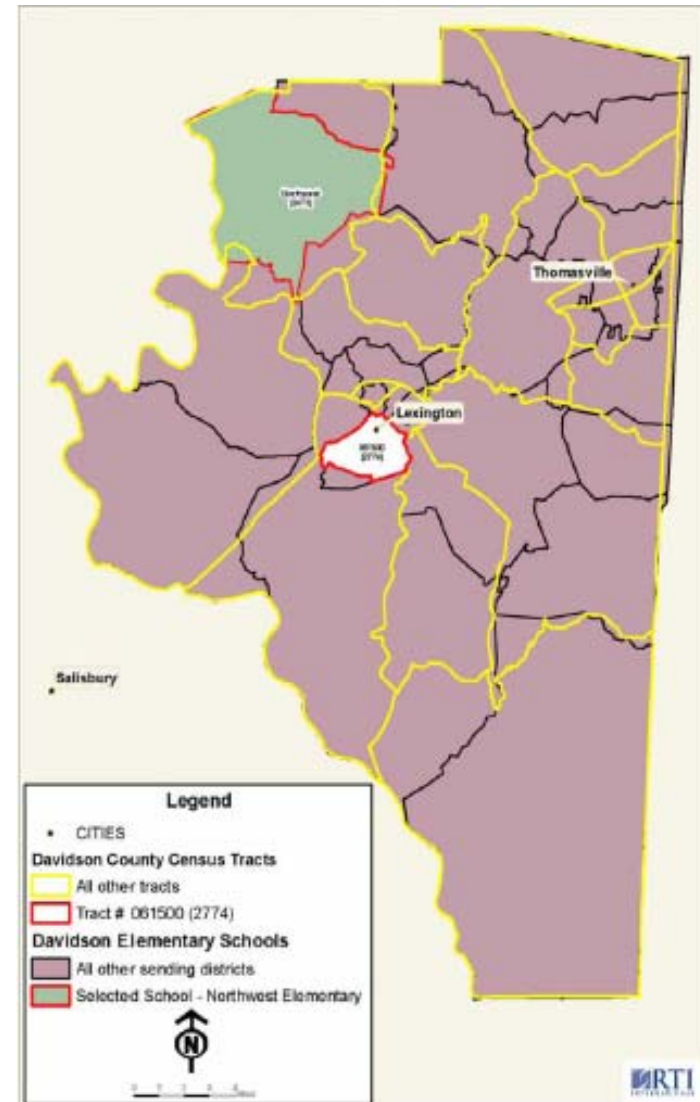
Forsyth County

- Both segments chosen in urban Winston-Salem
- Demographics are similar to facilitate comparisons between the two types of segments



Davidson County

- Rural county
- Census tract in Lexington
 - Characteristic of a small town
- School catchment area in rural Northwest



Birth Hospitals

Forsyth Residents

92.7% deliver at Forsyth Memorial

Davidson Residents

34% deliver at Lexington Memorial

17.5% at Forsyth Memorial



Demographics



Name	Total Number of Households	Percent White	Percent African American	Percent Hispanic	Percent Rural Housing	Percent Below Poverty
Forsyth						
North Hills / Kimberly Park	2992	11.5	71.3	15.4	0	23.3
Census (4 tracts)	2635	28.4	50.3	18.8	0	38.2
Davidson						
Northwest	2473	96.0	1.7	1.3	100	4.6
Census (1 tract)	2774	45.2	42.2	10.3	2.6	19.3*

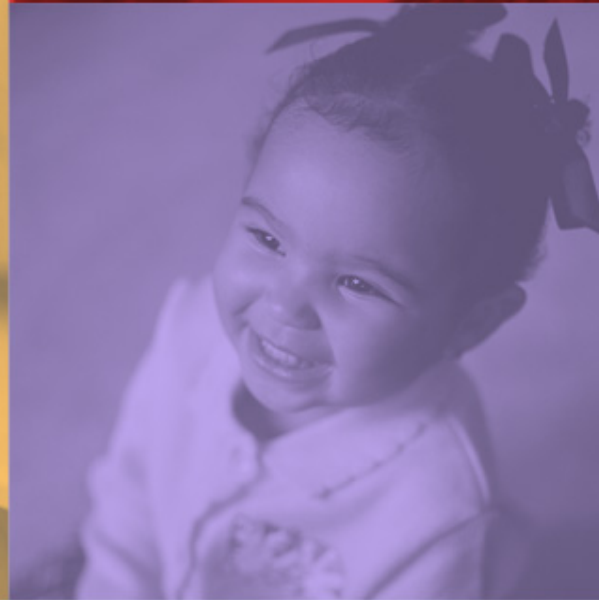
*10% > \$100K



Estimated Sample Size

- 10,000 households screened
- 950 eligible women enrolled
 - 170 High likelihood
- 400 infants





NC Pilot Study Plan



Start with the NCS Study Plan

- Preconception to 18 month visit
- Reviewed the Study Plan
- Associated workshop reports and expert panel recommendations
- Focus on elements related to burden, time and cost
 - Schedule of visits
 - Types and frequency of measures
- Focus on domains that might yield data of interest to a smaller study



What's different?

- Accelerated enrollment of pregnant women including some women at delivery
- No women under 18
- Focus on logistics/burden, not hypotheses



Eligible Study Participants

- Women likely to become pregnant
 - High likelihood: planning pregnancy
 - Moderate likelihood: no contraception or a technique with $>10\%$ failure rate
 - Low likelihood: contraception technique with $<10\%$ failure rate or not sexually active (not enrolled/consented but may be recontacted)
- Women who are pregnant
- Women who have recently given birth, and are still at the hospital for the delivery



Types of Data Collection



- Questionnaires and Interviews
 - In-person administered questionnaires
 - Using audio self-computer aided interview for sensitive topics
 - Mail-back questionnaires for diet and mental health
 - Event form
 - 30 data collection instruments total



Questionnaire Domains

- Acceptability – maternal and partner
- Activity – maternal
- Alcohol – maternal and partner
- Chemical exposures – maternal and partner
- Child development
- Demographics
- Dental Health
- Diet – child
- Diet – maternal SAQ
- Diet - maternal



Questionnaire Domains

- Feelings about pregnancy – maternal and partner
- Health care
- Home environmental conditions
- Household composition
- Infant safety
- Medical history (personal and family) – maternal and partner, child
- Medications (Rx and OTC) – maternal
- Mental health (SAQ) – maternal and partner
- Neighborhood



Questionnaire Domains

- Occupation – maternal and partner
- Partner updates
- Pets and pests
- Post-partum depression
- Reproductive health
- Supplements and vitamins – maternal
- Tobacco (self and ETS) – maternal and partner



Other Measures



Biologic Samples

Blood

Breast milk

Hair and nails

Urine

Vaginal swab, or
Semen

Cord blood and cord
sample

Placenta and photo

Saliva/buccal cells

Meconium

Environmental Samples

Air?

Surface and floor dust

Soil

Water

Physical Exam

Anthropometrics

Blood pressure and pulse

Ultrasounds

Community Measures

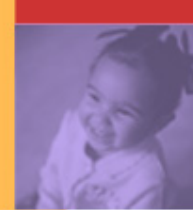
Routine monitoring

Groceries

Administrative data



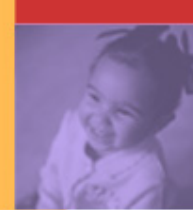
Overview of Study Visits: Preconception



Time of Visit	Contact Type	Visit	Length of Visit	Likelihood Group
Initial	Home	Screening	10 mins	---
2 weeks	Home	Interview	2.5 hrs	High, Mod
6 weeks	Telephone	Phone	5 mins	High
10 weeks	Home	Interview	1.5 hrs	High
14 weeks	Telephone	Phone	5 mins	High, Mod
18 weeks	Home	Interview	1.5 hrs	High
22 weeks	Telephone	Phone	5 mins	High
26 weeks	Home	Interview	1.5 hrs	High
26 weeks	Telephone	Phone	5 mins	Mod
38 weeks	Telephone	Phone	5 mins	Mod
50 weeks	Telephone	Phone	5 mins	Mod, Low



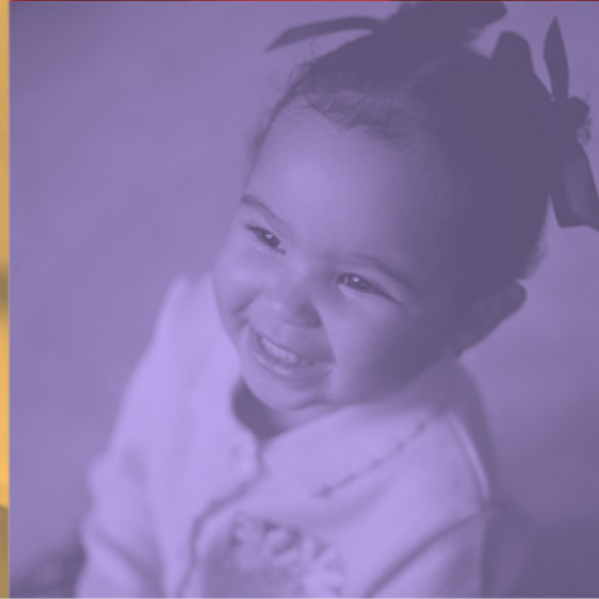
Overview of Study Visits: Pregnancy and Childhood



Time	Contact	Visit	Length of Visit
1st Trimester	Home	Pregnancy #1	1.5 hrs**
1st Trimester	Clinic	Oral Glucose Tolerance Test*	2.5 hrs
2nd Trimester	Clinic	Pregnancy #2	3 hrs
3rd Trimester	Clinic	Pregnancy #3	3 hrs
Birth	Clinic/Hospital	Birth Visit	30 mins
1 Month	Home	1 Month	1 hr**
6 Months	Home	6 Months	2 hrs
12 Months	Home	12 Months	1.5 hrs
18 Months	Home	18 Months	2 hrs

**15 minutes longer if first home visit





Timeline

Time Line

2004

March	Expert sampling panel
July	ICC explores options for a pilot cohort
September	First proposal reviewed by ICC/PO

2005

February	ICC approves pilot
March	NCSAC subcommittee concept clearance
April	First federal register notice (60 day public comment)
August	Finalize questionnaires (30) and submit for EPA review
September	Second federal register notice (30 day public comment) and OMB
October	Privacy Impact Assessment completed
November	IRB review and approval

2006

January	Counting and listing
March-June	Household screening and recruitment period

2007

September	Estimated last baby born to enrolled women
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Study Team

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Kristen Rappazzo, ASPH fellow at EPA

Lynne Messer, UNC Postdoc at EPA

Ann Williams, EPA field studies coordinator

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Ruth Brenner, NIH

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Jerry Rench, Project Manager

Sue Pedrazzani, Clinical Coordinator

Margie Byron and Roy Whitmore, Sampling Statisticians

